

Reviewer: _____ ORNL
Risk Manager (EPA): 25

Date: July 15, 2008

STUDY TYPE: Acute Inhalation Toxicity – Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Paraquat 43.8% Tech (~48% paraquat dichloride; Lot No. not reported, PSL Reference No. 061026-4G; dark green liquid, pH 3.98 as a 1% w/w solution, soluble in water)

CITATION: Lowe, C. (2007) Paraquat 43.8% Tech – Acute Inhalation Toxicity Study in Rats – Limit Test. Study Number 21079. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. March 14, 2007. MRID 47091109.

SPONSOR: Source Dynamics LLC, 10039 E. Troon North Drive, Scottsdale, AZ 85262

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47091109), five male and five female young adult Sprague-Dawley rats (age: 9-10 weeks; body weight: males: 297-352 g and females: 226-246 g; source: Ace Animals, Inc., Boyertown, PA) were exposed nose-only inhalation to Paraquat 43.8% Tech (~48% paraquat dichloride; Lot No. not reported) for 4 hours and 1 minute at a concentration of 0.051 mg/L. The animals were observed for 14 days. The MMAD was 2.1 and 2.2 μ m and the GSD 2.14 and 2.02 at 1.5 and 3 hours, respectively.

All males and four females died within 2-4 days following exposure and one female was emaciated and euthanized on day 7. All animals exhibited abnormal respiration, facial staining, hypoactivity, piloerection, and reduced fecal volume within one day of exposure. All animals had discolored lungs, liver, and/or intestines; edematous lungs; intestines distended with gas; and/or rigor mortis at necropsy.

LC₅₀ Males < 0.051 mg/L
LC₅₀ Females < 0.051 mg/L
LC₅₀ Combined < 0.051 mg/L

Paraquat 43.8% Tech is in EPA Toxicity Category I.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

| Nominal Conc. (mg/L) | Gravimetric Conc. (mg/L) | MMAD μm | GSD | Mortality/Number Tested | | |
|----------------------|--------------------------|--------------------|------------|-------------------------|---------|----------|
| | | | | Males | Females | Combined |
| 6.43 | 0.051 | 2.1, 2.2 | 2.14, 2.02 | 0/5 | 0/5 | 0/10 |

Test Atmosphere / Chamber Description: The exposure atmosphere was generated using a 1/4 inch JCO atomizer (Spraying Systems Co.), FC3 fluid cap (Robert Miller Associates) and 70 SS air cap (Spraying Systems Co.). The test material was metered to the atomization nozzle through a syringe pump with a 60 mL plastic syringe. Filtered air was supplied by an air compressor connected to the spray atomization nozzle. Additional compressed mixing air was supplied from a compressed air tank. Animals were individually housed in polycarbonate holding tubes which were sealed to the chamber during exposure. The exposure chamber was a Mini Nose-Only Chamber (ADG Developments Ltd.).

| | |
|----------------------------------|-----------------|
| Gravimetric Conc. (mg/L): | 0.051 |
| Chamber Volume (L): | 6.7 |
| Total Airflow (L/min): | 25.7 |
| Temperature | 21-23°C |
| Relative Humidity | 35-38% |
| Time to equilibrium: | 1 minute |

Test atmosphere concentration: During exposure, gravimetric samples were collected five times from the breathing zone of the animals, using glass fiber filters. Filter papers were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration.

Particle size determination: Particle size was determined twice using an eight-stage Andersen cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes.

- A. Mortality:** All males and four females died within 2-4 days following exposure and one female was emaciated and euthanized on day 7 for humane reasons.
- B. Clinical observations:** All animals exhibited abnormal respiration, facial staining, hypoactivity, piloerection, and reduced fecal volume within one day of exposure.

- C. **Gross necropsy:** All animals had discolored lungs, liver, and/or intestines; edematous lungs; distended intestines with gas; and/or rigor mortis at necropsy.
- D. **Reviewer's conclusions:** This reviewer agrees with the study author regarding the acute inhalation LC₅₀.